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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,412	10/03/2001	Allan Asp	Pha-1626	2742

7590 10/06/2003

Amersham Pharmacia Biotech, Inc.  
800 Centennial Avenue  
Piscataway, NJ 08855

EXAMINER
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JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/970,412	ASP ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. In view of the Appeal Brief filed on June 6, 2003, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

2. Presently, claims 11-12 are pending and under consideration. Any rejections not reiterated in this action have been withdrawn. **This action is NON-FINAL.**

### ***Priority***

3. It is noted that the first line of Applicants' specification includes a specific reference to parent application 09/068,783. However, Applicants' specific reference to the parent application improperly indicates that the '783 application "is a national stage filing under 35 U.S.C. 371 claiming priority to international patent application no. PCT/SE96/01464, filed November 13, 1996." As the '783 application is the national stage of PCT/SE96/01464, the '783 application cannot claim priority to that same PCT application. See *MPEP* 1893.03(c), which states that "a national stage application submitted under 35 U.S.C. 371 may not claim benefit of the filing date of the

international application of which it is the national stage since its filing date is the date of filing of that international application.” Accordingly, the first line of Applicants’ specification should be amended to recite, e.g., “is a national stage filing under 35 U.S.C. 371 of international patent application no. PCT/SE96/01464, filed November 13, 1996....”

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-12 are indefinite over the recitation of the phrase “two amplification primers comprising one member of a specific binding pair, the member being of the same type for both primers” in claim 11. First, regarding the recitation “two amplification primers comprising one member of a specific primer,” it is unclear as to whether this recitation requires two different primer molecules, each comprising “one member of a specific binding pair...”, or whether the claims are drawn to two primers that together comprise “one member of a specific binding pair.” Second, regarding the recitation “the member being of the same type for both primers,” it is unclear as to whether this language requires a single molecule or identical molecules on each primer, or whether this language also encompasses, e.g., primers comprising two different binding pair members of the “same type” (for example, two different haptens, or two “binding pair

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members" that share the same binding partner, such as avidin and streptavidin, each of which binds biotin [see page 4 of the specification]). Clarification is required.

Claim 12 is indefinite over the recitation of the limitation "wherein the sequencing primers are differently labelled." This language does not make clear whether "the sequencing primers" are differently labeled as compared to the "two amplification primers," whether the claim requires that one or more sequencing primers be "differently labeled" as compared to one or more other sequencing primers contained in the claimed kit, or whether the claim requires that each sequencing primer included in the kit comprise a label that differs from that on each other sequencing primer. Accordingly, the structural requirements of the sequencing primers contained in the claimed kit are unclear.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren (WO 94/11529 [5/1994]).

It is first noted that the specification at page 4 teaches that a specific binding pair "can be any pair of compounds with strong interaction between the members of the pair," and discloses that exemplary specific binding pairs include both biotin-avidin and biotin-streptavidin. It is further noted that the instant claims recite the open transitional language "comprising," and are therefore sufficiently broad so as to encompass kits including both the components recited in the instant claims and any other reagents and materials.

Landegren discloses methods of nucleic acid sequencing in which a manifold, amplification primers, and sequencing primers are employed, and discloses kits comprising the manifolds and reagents employed in their methods (see entire reference, particularly the description of sequencing procedures at page 9, line 10 through page 11, line 28, and the disclosure of kits at page 11, lines 29-32). In particular, Landegren discloses the use in nucleic acid sequencing of a manifold comprising multiple streptavidin-coated teeth, and two biotin-labeled primers, each of which is employed in a PCR with an unlabeled primer to produce sequencing templates that are captured using the manifold (see page 9, lines 13-30, as well as Figures 1-3). It is noted that while Landegren does not specifically refer to two different biotin-labeled primers, the specification teaches that PCR products serving as sequencing templates are produced

with one biotin-labeled primer and one unlabeled primer, and exemplifies the sequencing together of two different PCR products produced in this manner (a "first PCR reaction product" and a "second PCR reaction product"; see page 9, lines 13-30, and Figures 1-3); accordingly, Landegren discloses the use of "two amplification primers comprising one member of a specific binding pair, the member being of the same type for both primer," as required by the claims. Further, the multi-toothed manifold disclosed by Landegren constitutes both a "solid support" as required by claim 11 and a "manifold having a plurality of individual solid phase members," as set forth in claim 12. Landegren further discloses the sequencing of their captured templates using any one of several well known methods (see page 9, line 31-page 11, line 28), including a procedure that employs "four differently labeled primers" (see page 11, lines 16-23). Accordingly, Landegren discloses the use with their manifold and amplification primers of sequencing primers that are "differently labeled," which sequencing primers meet the requirements of both claims 11 and 12. Landegren discloses that in the practice of his method, reagents, including both amplification primers and sequencing primers, are provided in sets of wells (see, e.g., page 9, lines 14-24 regarding amplification primers, and page 9, line 31-page 10, line 1 and page 11, lines 16-26 regarding sequencing primers). Regarding kits, Landegren states "Advantageously, the manifolds and well sets may be provided in a kit form, which preferably has the necessary reagent components present in a dried state in the wells and/or on the solid phase members" (see page 11, lines 29-32). While Landegren does not exemplify a kit comprising the specific components set forth in the instant claims, given Landegren's own teachings, it

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would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have prepared such a kit. Landegren discloses a nucleic acid sequencing method in which a manifold, amplification primers, and sequencing primers meeting the requirements of the claims are employed together, and Landegren further teaches that it is advantageous to provide their manifolds, as well as "well sets" comprising the reagents necessary to practice their methods, in kit form. One of ordinary skill in the art would have been motivated to have prepared a kit comprising the reagents necessary to practice any of the various embodiments of Landegren's invention -- including a kit comprising a multi-toothed manifold, two biotin-labeled amplification primers, and multiple differently labeled sequencing primers, which kit is encompassed by the instant claims -- because Landegren specifically teaches that it would be advantageous to do so.

### **Conclusion**

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ahern (The Scientist 9(15):20 [7/1995]) teaches that premade reagents provided in kits that supply "all of the necessary reagents for a particular research application" are convenient and save researchers time and money (see entire reference, particularly p. 3/5-4/5).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

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Application/Control Number: 09/970,412  
Art Unit: 1634

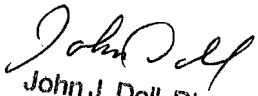
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen  
September 24, 2003

  
GARY BENZION, PH.D  
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